(18)

No. 00-151

IN THE
Supreme Court of the United States

UNITED STATES,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, *et al.*,

Respondent.

On Writ of Certiorari To The United States Court of Appeals For the Ninth Circuit

AMICUS CURIAE BRIEF OF THE MARIJUANA POLICY PROJECT AND RICK DOBLIN, PH.D AND ETHAN RUSSO, M.D. IN SUPPORT OF THE RESPONDENTS

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IDENTITY AND INTEREST OF *AMICI CURIAE*

The Marijuana Policy Project (MPP), Rick Doblin, Ph.D. and Ethan Russo,M.D., respectfully submit this brief as amici curiae in this case. Letters from Petitioner and Respondents

granting consent to the filing of this brief have been filed with this Court.[1]

MPP (www.mpp.org) is a non-profit, public interest advocacy organization representing more than 1,000 seriously ill people throughout the nation who are struggling to obtain legal access to medical cannabis. Since 1995, MPP and several of its seriously ill clients have met with officials from the FDA, the National Institutes of Health, and the National Institute on Drug Abuse (NIDA). MPP representatives have also testified before the National Academy of Sciences' Institute of Medicine (IOM) and the American Medical Association House of Delegates. MPP's clientele, like thousands of other patients nationwide, must choose between suffering or following their doctors' orders to use medical cannabis—even though the latter may result in a federal prison sentence. Consequently, MPP is exhausting all options to provide a legal avenue through which its clients may obtain and use medical cannabis.

Rob Kampia is the co-founder and executive director of MPP.

Rick Doblin has a Ph.D. in Public Policy from the Kennedy School of Government, Harvard University. He is the founder and current director of the Multidisciplinary Association for Psychedelic Studies (MAPS, www.maps.org), a non-profit membership-based research and educational organization and pharmaceutical company that works to develop cannabis and other Schedule I drugs into Food and Drug Administration (FDA)-approved prescription medicines. MAPS helped support the successful five-year struggle of Dr. Donald Abrams, University of California -San

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[1] Pursuant to Rule 37.6, Amici discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than Amici Curiae, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

Francisco, to obtain permission to conduct research into the effects of smoked cannabis in AIDS patients. Dr. Abrams' study, which treated the first patient in 1998, was the first FDA-approved study of the medical use of smoked cannabis in a patient population in twelve years. MAPS holds the only Orphan Drug designation granted by the FDA for any medical use of the cannabis plant itself, specifically in the treatment of AIDS patients suffering from HIV-related wasting syndrome. MAPS thus has a commercial interest in developing the cannabis plant into an FDA-approved prescription medicine for AIDS wasting, and potentially for other clinical indications as well. MAPS is preparing to submit an application to DEA to obtain permission for its own small medical cannabis production facility, to grow high-potency cannabis for FDA-approved protocols.

Ethan Russo, M.D.,is a Clinical Child and Adult Neurologist; Adjunct Associate Professor of Pharmacy, University of Montana, and editor of the *Journal of Cannabis Therapeutics*. Dr. Russo, with the support of MAPS, obtained FDA approval (IND #58,177) to conduct a human pilot study into the risks and benefits of smoked cannabis in patients suffering from treatment-resistant migraines. Despite FDA approval of his protocol, Dr. Russo was unable to conduct his research. NIDA, which holds a monopoly on the supply of cannabis approved by FDA for use in human clinical research, refused to sell any of its cannabis to Dr. Russo for use in his protocol.

SUMMARY OF THE ARGUMENT

The federal government, specifically the NIDA of the U.S. Department of Health and Human Services (HHS), retains a restrictive and unnecessary monopoly over the only supply of cannabis that at this time is allowed to be used in FDA-approved clinical trials. HHS and NIDA have exercised this monopoly over cannabis so as to impede the normal drug

development process contemplated by Congress. Most recently, NIDA and HHS have unreasonably imposed an additional layer of regulatory review over privately funded clinical research with cannabis. No other Schedule I drug has to endure such an obstacle course.

In the instant case, this Court is being asked to decide whether there is a medical cannabis necessity defense to the Controlled Substances Act, 21 U.S.C. 801 *et. seq.* Amici urge the Court to keep in mind that the FDA drug development process, the most direct and appropriate method for authorizing the provision of cannabis to patients with a legitimate, medical need for the drug, has been politically hobbled. The lack of FDA-approval of cannabis as a prescription medicine is due, in large part, to the systematic hindrance of scientific research by governmental agencies over the last several decades. The Court should not rule against a medical necessity defense based on the illusion of a well-functioning FDA-approval process. Executive branch obstructionism has made it necessary for the medical necessity defense to serve as a "safety net" for a limited number of patients.

THE ARGUMENT

I. THE MEDICAL NECESSITY DEFENSE IS THE ONLY REASONABLE ALTERNATIVE GIVEN THE GOVERNMENT'S OBSTRUCTION OF FDA-APPROVED RESEARCH INTO THE POTENTIAL THERAPEUTIC USES OF CANNABIS

A. An Agency of the Federal Government Has a Monopoly on the Legal Supply of Cannabis for Use in FDA-Approved Research.

The Single Convention on Narcotic Drugs, to which the United States is a Party, regulates the manufacture of

cannabis within the boundaries of the signatory nations.[2] Under Article 23 2(e) of the convention, a private, non-governmental organization can obtain permission from a Party to grow cannabis for licensed medical uses without the Party coming into violation of any of the provisions of the Convention. The non-governmental producer would not need to sell its output to the government and could distribute its stocks for medical purposes to the extent that it was licensed to do so. In order for a non-governmental producer to function in this manner, the government would need to extend formally its exclusive rights to manufacture and trade cannabis for medical purposes to the non-governmental entity.

In the United States, NIDA is the federal agency that has had a monopoly on the supply of FDA-approved research-grade cannabis for use in human subjects.[3] [4] Sponsors of research into the medical uses of cannabis cannot at present manufacture their own supplies of research material but must instead petition to purchase federal supplies at cost from NIDA. However, NIDA's institutional mission is to sponsor research into the understanding and treatment of the *harmful* consequences of the use of illegal drugs and to conduct educational activities to reduce the demand for and use of

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[2] Single Convention on Narcotic Drugs (US Treaty Series Vol. 520, US Treaties and other International Agreements. Vol 18 Part 2, 1967, p. 1407-1431.), which concluded on March 30, 1961, and entered into force in the United States on June 24, 1967. For the text of the treaty, *see* http://www.incb.org/e/ind_ar.htm

[3] NIDA contracts with the University of Mississippi to grow cannabis for research purposes, under the direction of Professor Mahmoud ElSohly. The University of Mississippi facility holds the only license issued by the DEA for the production of cannabis for human consumption.

[4] FDA has not permitted researchers to use seized marijuana for research purposes due to uncertain purity and the inability to conduct subsequent studies with a standardized and replicable product.

these illegal drugs. NIDA's mission makes it a singularly inappropriate agency to be responsible for expeditiously stewarding scientific research into potential *beneficial* medical uses of cannabis. Furthermore, as with many monopolies, the quality of its product is low, [5] and access is restricted.

In contrast, in England, which is also a Party to the Single Convention, the Home Office in 1997 granted a license to GW Pharmaceuticals, a non-governmental for-profit corporation, to grow cannabis for the manufacture of cannabis extracts to be used in clinical trials.[6]

MAPS is preparing to apply to the Drug Enforcement Administration (DEA) for a license to establish a small, medical cannabis production facility to supply high-quality research material to researchers with FDA-approved protocols. This facility will most likely take several years or more to become approved and operational, if ever. For the foreseeable future, NIDA will continue to exert undue control over medical cannabis research as a result of its monopoly over the supply of cannabis.

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[5] MAPS and California NORML conducted a scientific study of the potency of cannabis used by patients across the country. This potency was then compared to the average potency of the cannabis that NIDA provides to the eight remaining patients who are part of the Compassionate Investigational New Drug program. Patients preferred cannabis that was roughly three to four times more potent than what NIDA supplies. The primary advantage of more potent cannabis is that it enables patients to inhale less smoke and particulate matter per unit of therapeutic cannabinoids. Gieringer D. *Medical Cannabis Potency Testing Project*, MAPS 9 (1999) 3:20-22. http://www.maps.org/news-letters/v09n3/09320gie.html

[6] See website of GW Pharmaceutical company's non-profit arm, the UK Medicinal Cannabis Project: http://www.medicinal-cannabis.com/project/main.html

B. FDA-Approved Research into the Therapeutic Uses of Cannabis Has Been Blocked by NIDA.

Ideally, after a physician has determined that a patient has a medical need for the use of the cannabis plant, the patient should be able to obtain it in the form of an FDA-approved prescription medicine that is standardized for purity and potency. For this outcome to be realized, a pharmaceutical company must first submit to FDA sufficient scientific data proving safety and efficacy in a specific patient population, with the data gathered in controlled clinical trials conducted with prior approval of the FDA and DEA. [7] [8]

Despite persisting interest in the medical research community into the exploration of the medical uses of cannabis, not one single patient in the United States received cannabis in the context of an FDA-approved study during the 12-year period between 1986—when the last of the state studies concluded into the use of smoked cannabis in controlling nausea and vomiting in cancer chemotherapy patients[9]—and 1998, when Dr. Donald Abrams at the University of California—San Francisco administered smoked cannabis to the first AIDS patient in his

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[7] See FDA Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products. http://www.fda.gov/cder/guidance/1397fnl.pdf

[8] MAPS and California NORML are sponsoring research into the use of vaporizer technology to heat the cannabis plant but not burn it. Preliminary evidence demonstrates that the vaporizer can release clinically significant amounts of cannabinoids without generating the compounds that come from combustion This is part of an effort to develop non-smoking delivery systems for the cannabis plant.

[9] Randall R. *Marijuana, Medicine & the Law Volume 2*. Washington, DC: Galen Press, 1989, 250. The States were California, New York, New Mexico, Tennessee, Georgia, Michigan and Washington.

groundbreaking study.[10] Dr. Abrams had to struggle for five years to obtain permission to conduct his study, three years of which was after his initial protocol had been approved by FDA. In order to proceed at all, NIDA demanded that Dr. Abrams transform his FDA-approved protocol, designed to assess safety and efficacy in AIDS wasting patients, into a safety study primarily evaluating the risks of cannabis in AIDS patients who did not suffer from AIDS wasting syndrome.[11]

In response to NIDA's reluctance to provide cannabis for medical research into its potential medical uses, the American Medical Association House of Delegates in December 1997 passed the following resolution:

> That the AMA urge the National Institutes of Health (NIH) to implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research into the medical utility of marijuana. This effort should include: . . . (c) confirming that marijuana of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the Drug Enforcement Agency [sic] who are conducting bona fide clinical research studies that receive Food and Drug Administration approval, regardless of whether or not the NIH is the primary source of grant support.[12]

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[10] Abrams D. Medical Cannabis:Tribulations and Trials.*Journal of Psychoactive Drugs* 30 (Apr-Jun 1998) 2:163-9.

[11] Leshner A. Director of NIDA. Letter to Dr. Donald Abrams. April 19, 1995. http://www.maps.org/mmj/leshner.html; Abrams D. Letter to Dr. Leshner, Director of NIDA. April 28, 1995. http://www.maps.org/mmj/abrams.html.

[12] Council on Scientific Affairs Report 10 - Medical Marijuana, Recommendations, passed by AMA House of Delegates, December 9, 1997.

C. HHS's 1999 Guidelines Restrict Rather than Facilitate FDA-Approved Research.

In December 1999, HHS finally implemented a new written policy regarding the provision of cannabis to FDA-approved researchers, allegedly to expedite FDA-approved medical cannabis research.[13] Rather than announce that NIDA would supply cannabis for free or at cost to all FDA-approved protocols, HHS added yet another layer of bureaucratic review.

HHS's guidelines require sponsors of privately funded and FDA-approved protocols who seek to purchase supplies from NIDA to submit their protocols for review and approval to the Public Health Service (PHS), an additional review process that exists exclusively for cannabis research.[14] HHS guidelines also specified a limited number of medical conditions for which cannabis should be tested, recommended that protocols be designed to prove cannabis equal or superior to existing medications despite FDA's statutory requirement to approve drugs if they are proven safe and efficacious as compared to placebo (since some patients may respond best to a medicine that is not on average equal to or better than other medicines), suggested that researchers conduct only "multi-patient" studies rather than "single-patient" studies which FDA also considers scientifically valid, and discouraged researchers from conducting studies with the goal of getting natural cannabis approved as a prescription medicine. None of these restrictions apply to research with any other substance, even those in Schedule I.

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[13] Guidance On Procedures for the Provision of Cannabis for Medical Research. Department of Health and Human Services. May 21, 1999. http://www.mpp.org/guidelines/hhsguide.html

[14] The new HHS guidelines read, "After submission, the scientific merits of each protocol will be evaluated through a Public Health Service interdisciplinary process." [section III, second paragraph].

John Benson, M.D., principal investigator of the 1999 IOM report on medical cannabis, commented that "it's hard to discern that these guidelines have streamlined existing procedures."[15]

Almost immediately, HHS's policy had a chilling effect on medical cannabis research. In September 1999, Dr. Ethan Russo received FDA approval for a protocol designed to examine the medical uses of cannabis in treatment-resistant migraine patients, an indication for which cannabis was utilized in mainstream Western medicine between 1842 and 1942.[16] In February 2000, NIDA refused to supply Dr. Russo with the necessary cannabis, based on criticisms of the protocol design by the PHS reviewers.[17] Since Dr. Russo's protocol was approved by FDA and would have been privately funded, the decision by PHS and NIDA not to provide the cannabis at cost effectively halted the standard FDA drug development process.

For the foreseeable future, medical research with cannabis will proceed only as far and as fast as NIDA and HHS permit, regardless of the willingness of FDA to allow clinical trials to move forward.

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[15] McMahon, P., Oregon, Alaska Identify Legal Marijuana Users on State-Issued Cards. USA Today, May 24, 1999, A 4.

[16] McCormick C. Director of FDA Division of Anesthetics, Critical Care and Addiction Drug Products. Letter to Dr. Ethan Russo. Sept. 21, 1999. Re: IND #58,177. See also, Russo, E.B., Cannabis for Migraine Treatment: The Once and Future Prescription?: An Historical and Scientific Review, *Pain* 36(1):3-8, 1998, or available at: http://www.druglibrary.org/crl/pain/Russo%2098%20Migraine_%20Pain.pdf

[17] Mann L. Public Health Service, Center for Scientific Review. Summary Statement: Cannabis in Acute Migraine Treatment Project. Letter to Dr. Russo. February 1, 2000. http://www.maps.org/mmj/russo1199/02010001.html

D. HHS's Policy Makes it More Difficult to Research Cannabis Than Any Other Drug, Including All Other Schedule I Drugs.

Within the last ten years, FDA has approved several privately funded protocols involving the use of Schedule I substances such as MDMA (Ecstasy),[18] psilocybin,[19] and ibogaine.[20] Each of these studies was or will be conducted with compounds obtained from private, non-governmental DEA-licensed manufacturers. The lack of an independent source of cannabis for use in FDA-approved clinical trials is an aberration and not the norm for Schedule I drugs.

E. Given the Difficulty of Conducting FDA-Approved Research, It is Unlikely that the FDA Will Be Able to Approve Cannabis as a Prescription Medicine in the Near Future, If Ever.

In January 1997, in response to the passage of Proposition 215 in California, the White House Office of National Drug Control Policy commissioned IOM to conduct a one-million-dollar study into the therapeutic uses of cannabis. In March

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[18] Approved November 5, 1992. IND #39,383. A Phase 1 dose-response safety study conducted by Dr. Charles Grob, Harbor UCLA. The MDMA was manufactured under DEA license by Dr. David Nichols, Dept. of Medicinal Chemistry, Purdue University.

[19] ND # 56,530. McCormick C. Director of FDA's Division of Anesthetics, Critical Care and Addiction Drug Products. Letter to Dr. Francisco Moreno. Sept 17, 1998. This protocol was approved but put on hold until a source of psilocybin could be arranged. MAPS has arranged for Organix, Inc. of Woburn, MA to manufacture the psilocybin

[20] On August 25, 1993, the FDA Drug Abuse Advisory Committee meeting recommended approving the Phase 1 dose- response safety study proposed by Dr. Juan Sanchez-Ramos and Deborah Mash, Ph.D., U. of Miami Medical School. The ibogaine for this study was imported by the researchers from Europe, with DEA approval.

1999, IOM released its report [21] which had the following to say about the likelihood of the FDA being able to approve cannabis as a prescription medicine:

> [R]esearch funds are limited, and there is a daunting thicket of regulations to be negotiated at the federal level (those of the Food and Drug Administration, FDA, and the Drug Enforcement Administration, DEA) and state levels. [p. 137]
>
> Some drugs, such as marijuana, are labeled Schedule I in the Controlled Substance Act, and this adds considerable complexity and expense to their clinical evaluation. [p. 194]
>
> From a scientific point of view, research is difficult because of the rigors of obtaining an adequate supply of legal, standardized marijuana for study. [p. 217]
>
> In short, development of the marijuana plant is beset by substantial scientific, regulatory, and commercial obstacles and uncertainties. [p. 218]
>
> [D]espite the legal, social, and health problems associated with smoking marijuana, it is widely used by certain patient groups. [p. 7]

Consequently, patients who are already medicating with cannabis under their doctors' supervision have little hope that the FDA drug-approval process will result in cannabis being made available as a prescription medicine. This pessimistic outlook has nothing to do with the actual therapeutic potential of cannabis, and has everything to do with political obstacles that have subverted the FDA drug-approval process.

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[21] Joy J, Watson S, Benson J (eds.): *Cannabis and Medicine: Assessing the Science Base*, Washington, DC: Institute of Medicine, National Academy Press, 1999. http://stills.nap.edu/books/0309071550/html

F. The Executive Branch Disregarded the Institute of Medicine's Recommendation to Provide Immediate Access to Medical Cannabis on a Case-By-Case Basis.

The 1999 IOM report made the following recommendations about research into the medical uses of cannabis:

> [I]t will likely be many years before a safe and effective cannabinoid delivery system, such as an inhaler, is available for patients. In the meantime there are patients with debilitating symptoms for whom smoked marijuana might provide relief.
>
> Until a non-smoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting. One possible approach is to treat patients as n-of-1 clinical trials (single-patient trials), in which patients are fully informed of their status as experimental subjects using a harmful drug delivery system, and in which their condition is closely monitored and documented under medical supervision.
>
> Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions: failure of all approved medications to provide relief has been documented; the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs; such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness... (p. 7-8)[22]

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[22] *Ibid.*

Two months later, HHS released its medical cannabis research guidelines, which formally took effect in December 1999. HHS's policy reads, in part:

> HHS intends to direct its program toward multi-patient clinical studies. As previously determined by [PHS], single-patient requests for marijuana raised a number of concerns including the fact that the single-patient IND process would not produce useful scientific information and we do not foresee that they would be supported under this program.[23]

Hence, the executive branch has not only shown its willingness to block congressional intent, but it has also disregarded the findings of the IOM of the National Academy of Sciences, chartered by Congress in 1863 to advise federal agencies.

II. BECAUSE THE FDA DRUG DEVELOPMENT PROCESS IS NOT WORKING AS CONGRESS INTENDED, PATIENTS WHO FOLLOW THEIR DOCTORS' ORDERS TO OBTAIN CANNABIS THROUGH ALTERNATIVE MEANS SHOULD BE PERMITTED TO OFFER A MEDICAL NECESSITY DEFENSE

Thousands of seriously ill people nationwide are already using cannabis to treat their medical conditions. Many—if not all—of these patients would prefer to receive their medication through pharmacies. Short of that, many patients would appreciate the opportunity to participate in FDA-approved research as a means of gaining temporary, legal access to cannabis. Having been thwarted by bureaucratic obstacles impeding recourse through the FDA, medical cannabis

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[23] Guidance On Procedures for the Provision of Cannabis for Medical Research. Department of Health and Human Services. May 21, 1999, section IV, fourth paragraph.

patients currently have no practicable option but for the medical necessity defense.

Patients whose physicians consider their use of cannabis to be necessary for the treatment of their illnesses must risk criminal sanctions to obtain the relief they deserve. As the Court considers the viability of the medical necessity defense, it should consider that the lack of sufficient scientific data from FDA-approved controlled clinical trials to justify FDA-approval of cannabis as a prescription medicine is in large part due to the hindrance of research over the last several decades. Moreover, HHS's 1999 policy imposed yet another layer of regulatory review over privately funded clinical research with cannabis, more burdensome than for research with any other drug.

Given the difficulties of conducting FDA-approved research into the medical uses of cannabis because of the past and continuing supply problems and HHS' unique and restrictive guidelines, it is unrealistic to expect that patients who have a legitimate medical need will be able to obtain temporary legal access to cannabis via FDA-approved research in any substantial way. And, even if the FDA were disposed to approve cannabis as a prescription medicine many years from now, the Court should allow the medical necessity defense to be raised in the meantime.

The Court should not rule against a medical necessity defense based on the illusion of a well-functioning FDA-approval process. Executive branch obstructionism has made it necessary for the medical necessity defense to serve as a "safety net" for a limited number of patients.

CONCLUSION

For the foregoing reasons, Amici ask this Court to affirm the judgment of the court of appeals.

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